K123866

510(k) Summary

**Date of Submission:** November 28, 2012

**Submitter:** Medecell US, Inc.
4901 Boulder Lane
Hoffman Estates, IL 60010-5842
Phone: +1-847-323-5599
**Contact Person:** Robert Da Rocha, International Director

**Subject Device:**
Proprietary Name: Tanyx®
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation: 882.5899
Product Code: NUH

SEP 13 2013

**Predicate Devices:**
*Name of device* *Model PM3030*
Manufacturer: Omron Health Care
K number: K110068
Product Code: NUH

**Device Description:**
**TANYX®** is based on TENS medical technology. The purpose of the product is to reduce or eliminate pain through the emission of controlled and focused electrical signals. It is a disposable device, designed to be sold directly to consumers for the temporary relief of pain. **TANYX®** adheres to a person's skin and emits either a fixed or modulated electrical signal through a grid of integrated electrodes. It is a product which is characterized as portable, inexpensive, disposable, and (compared to other TENS-based products) easy to handle and operate. No medical supervision is required.

**Intended Uses:**
"To be used in adults only for temporary relief of pain associated with sore and aching muscles in the upper extremities (arms), lower extremities (legs), and lower back due to strain from exercise or normal household and work activities."

**Summary of Technological Characteristics:**

| | Model PM3030 | TANYX® |
|---|---|---|
| | Manufacturer: Omron Healthcare, Inc. | Manufacturer: Medecell do Brasil |
| | K110068 | |
| **Indications for Use** | This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities. | To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arms), lower extremities (legs), and lower back due to strain from exercise or normal household and work activities. |
| **Patient Population** | Adults | Adults |
| **Prescriptive or OTC** | OTC | OTC |
| **Environment Of use** | Clinics, hospital and home environments | Clinics, hospital and home environments |
| **Number Of Output modes** | 3 | 6 |
| **Number of output channels** | 1 | 1 |
| **Waveform** | Biphasic | Monophasic |
| **Shape** | Rectangular | Rectangular |
| **Maximum Output Voltage (max)** | | |
| **500 ohm** | 35.4 V | 47.6 Vpp |
| **2k ohm** | 46.7 V | 64.0 Vpp |
| **10k ohm** | 50.8 V | 72.8 Vpp |
| **Frequency (Hz)** | 0-100 Hz | 55 Hz |
| **Maximum Output Current (max)** | | |
| **500 ohm** | 4.4 mA | 95.2 mApp |
| **2k ohm** | 1.7 mA | 29.1 mApp |
| **10k ohmn** | 0.4 mA | 7.9 mApp |
| **Maximum Average Current** | 3.5mA | 6.02mA |
| **Maximum Current Density** | 0.095mA/$Cm^2$ | 0.12mA/$Cm^2$ |
| **Maximum Average Power Density** | 89mW/$Cm^2$ | 98mW/$Cm^2$ |
| **Maximum Phase charge (500 ohm)** | 1 33 µC | 0.19 µC |
| **Burst Mode** | none | yes |
| **Timer range (min)** | 15 minutes | No |
| **Dimensions** | 55 mm x 95 mm x 19mm | 153mm x 51mm x 8.2mm |
| **Weight** | 60 grams | 30 grams |
| **Material** | Acrylonitrile Butadiene Styrene (ABS) | Acrylonitrile Butadiene Styrene (ABS) and Polypropylene (PP) |
| **Microprocessor control** | Yes | yes |
| **Automatic Overload trip** | Yes | No |
| **Automatic no-load trip** | Yes | Yes |
| **Automatic shut-off** | Yes | No |
| **User control** | Power On/Off button | Power On/Off and Intensity buttons |
| **Electrode cable** | Yes | No |

**Differences between Tanyx and Predicate Device**

Tanyx is viewed as substantially equivalent to the predicate device because the stimulation parameters are all in the same range for the intended use. The device includes a wide variation in terms of Current, Voltage Amplitude and Waveform, the basic parameters, without sacrificing biological effects. Maximum Output Current differences between Tanyx and the predicate device are due to different measurement methods. Tanyx was measured using a peak-to-peak value and predicate device uses RMS value, but both devices are in the same range of safety and efficacy. Other measurement differences are not significant from the predicated device. Operation and mechanical design don't show significant differences.

**Non-Clinical Performance Data:**

| Characteristic | Predicate | Subject |
|---|---|---|
| | | |
| *Biocompatibility* | | |
| ISO 10993-1 | Passed | Passed |
| ISO 10993-5:2009 | Not specified | Passed |
| ISO 10993-10:2010 | Not specified | Passed |
| | | |
| *Device Safety* | | |
| IEC 60601-1 | Passed | Passed |
| IEC 60601-2-10 | Passed | Passed |
| | | |
| Hazard Analysis | | |
| ISO 14971:2007 | Not Specified | Passed |

**Risk Analysis Method:**
The hazard analysis for the device was conducted according to EN ISO 14971:2007. The device was found to adequately minimize the risks for shock and burn as identified by FDA.

**Usability Study:**
A usability study was conducted and showed that users were able to use the device correctly and safely.

**Conclusion:**
**Tanyx®** is substantially equivalent to a legally marketed device. Although it has some technological characteristics that differ from that of predicate, TENS current state of art support that stimulation parameters of both devices are in the same range for the intended biological effects and practical use and raises no new questions of safety and effectiveness.

## Summary of substantial equivalence

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| | | |
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| **Electrode cable** | Yes | No |

Our product Tanyx was tested by the company "No Risk" from Brazil resulting the report ***R120331 - Medecell - Stimulator - Tanyx - parameters – 12042710***. The numbers collected from this document demonstrate that Tanyx is in accordance to the limits established to the safety of the patient. The differences between Tanyx and the other device, we believe do not raise any new question regarding safety and effectiveness because both are under the established limits.

In reference to the MAXIMUM OUTPUT VOLTAGE, our product have numbers under established limits within industry standards and the differences between the devices do not raise any new question of safety and effectiveness.

Regarding the MAXIMUM OUTPUT CURRENT, Tanyx again have our numbers under the established limits and the differences between the devices do not raise any new question of safety and effectiveness because both products are in accordance to industry standards.

Referent to the MAXIMUM PHASE CHARGE, the number for Tanyx is over the established limit and again, the difference between the devices do not raise any question regarding safety and effectiveness because both are under limits.

Regarding the MAXIMUM CURRENT DENSITY of Tanyx, the product is under the maximum limits and because of this do not raise any new question of safety and effectiveness. The differences between the devices do not raise any new question too, because both are under the maximum limits established.

In reference to MAXIMUM AVERAGE CURRENT, Tanyx is under the established maximum limits. The differences between the products do not raise new questions of safety and effectiveness because, as Tanyx, the other device is under the maximum limits.

Regarding MAXIMLUMN AVERAGE POWER DENSITY, the product is under the maximum limits and because of this do not raise any new question of safety and effectiveness. The differences between the devices do not raise any new question too, because both are under the maximum limits established.

In reference to Frequency (Hz) Tanyx has a 55 Hz (this number may vary ± 3%) and this frequency do not raise any new question of effectiveness and safety because it is tested and the differences between the devices to not raise any question two because they are under the limits of patient safety.

Tanyx is viewed as substantially equivalent to the predicate device because the stimulation parameters are all in the same range for the intended use. The device includes a wide variation in terms of Current, Voltage Amplitude and Waveform, the basic parameters, without sacrificing biological effects. Maximum Output Current differences between Tanyx and the predicate device are due to different measurement methods. Tanyx was measured using a peak-to-peak value and predicate device uses RMS value, but both devices are

in the same range of safety and efficacy. Other measurement differences are not significant from the predicated device. Operation and mechanical design don't show significant differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Medecell
c/o Rhonda Alexander, M.S., M.P.A.
Registrar Corp
144 Research Drive
Hampton, VA 23666

Re: K123866
Trade/Device Name: Tanyx®
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 23, 2013
Received: July 24, 2013

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K123866

Device Name: Tanyx®

Indications For Use:

To be used in adults only for temporary relief of pain associated with sore and aching muscles in the upper extremities (arms), lower extremities (legs), and lower back due to strain from exercise or normal household and work activities.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S